

## **REMARKS**

The Office Action dated September 16, 2003 has been carefully considered. Claims 1, 2, 4-12, as amended herein, and new claims 37-46 are pending in the present application. Claims 13-36 have been withdrawn from consideration without prejudice. Claim 3 has been canceled, and claim 1 has been amended to incorporate the subject matter of canceled claim 3. New claims 37-46 have been added. These amendments and new claims find support in the original specification at, for example, original claims 1-12. Thus, it is believed that no new matter has been introduced.

Reconsideration of the present application and entry of the above amendments in view of the following remarks are respectfully requested.

### **I. REJECTION UNDER 35 U.S.C. § 102**

#### **A. Claims 1, 4 and 5 Are Patentable Over U.S. Patent No. 5,925,069 to Graves *et al.***

Claims 1, 4 and 5 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,925,069 to Graves *et al.* (“Graves”). This rejection is respectfully traversed.

Independent claim 1, as amended herein, recites a “method for manufacturing an implantable medical device having a surface adapted for exposure to body tissue of a patient, . . . comprising . . . applying to a portion of the surface of the first medical device a coating composition comprising the biologically active material in a manner such that a coating containing an amount of the biologically active material in excess of the desired amount of biologically active material is formed on the surface of the first medical device; [and] weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material . . . .” Claims 4 and 5 depend from claim 1 and, thus, also include these recitations of claim 1.

Unlike the method of claim 1, Graves does not disclose or suggest a method for manufacturing an implantable medical device that includes “weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material.” In fact, as acknowledged by the Examiner on page 8 of the Office Action, Graves does not disclose or suggest any method

for determining “the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material.”

Moreover, Graves teaches away from weighing or quantifying the amount of biologically active material in the coating before removal of the excess biologically active material in the coating. More specifically, Graves teaches that the configuration or amount of coating to be removed is determined by using a non-weighing or non-quantifying technique involving a stencil or mask. The stencil or mask determines the amount of coating to be removed without any measurement, by weighing or otherwise, of the amount of coating to be removed. (Column 4, lines 3-7). By teaching that such stencil or mask should be used, instead of weighing the amount of coating to be removed, Graves teaches away from the weighing step recited in claim 1.

Thus, it is believed that claim 1 and claims 4 and 5 depending therefrom are patentable over Graves. Accordingly, withdrawal of this rejection and allowance of claims 1, 4 and 5 are respectfully requested.

**B. Claims 1, 4, 5, And 12 Are Patentable Over U.S. Patent No. 6,503,556 To Harish *et al.***

Claims 1, 4, 5, and 12 have been rejected under 35 U.S.C. 102(e) as allegedly being anticipated by U.S. Patent No. 6,503,556 to Harish *et al.* (“Harish”). This rejection is respectfully traversed.

As stated above, independent claim 1, as amended herein, recites “applying to a portion of the surface of the first medical device a coating composition comprising the biologically active material in a manner such that a coating containing an amount of the biologically active material in excess of the desired amount of biologically active material is formed on the surface of the first medical device; [and] weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material.” Claims 4, 5 and 12 depend from claim 1, and thus also include these recitations of claim 1.

Harish does not disclose or suggest applying to a surface of a medical device a coating composition comprising a biologically active material. Instead, Harish teaches first forming a composition which may contain an active ingredient into a sheath. (Col. 6, lines 65-66). The sheath is formed either by an extrusion or rolling technique. (Col. 7, lines 14-21). After the sheath has attained a tubular structure, it is then fitted over the stent and heated to form a coating on the medical device. (Col. 7, lines 1-2). Since the sheath must be

fitted over the stent after formation, “[t]he inner diameter of [the] sheath should be slightly larger than the outer diameter of [the] stent . . . .” (Col. 6, line 67- Col. 7, line 2). Thus, Harish does not disclose or suggest applying a coating composition comprising a biologically active material to a surface of a medical device to form a coating on the surface. Instead, Harish teaches using a sheath to form the coating.

Although Harish discloses applying an optional primer layer to the surface of the stent prior to insertion of the stent within the sheath, this primer layer does not contain any biologically active material. (Col. 8, lines 13-16). Harish states that “[t]he primer composition typically includes a polymer dissolved in a solvent.” (Col. 8, lines 43-44). Harish further discloses that “[t]he primer layer provides for an adhesive tie between [the] sheath and [the] stent.” (Col. 8, lines 24-25). Moreover, Harris discloses that “[t]he presence of an active ingredient in a polymeric matrix typically interferes with the ability of the matrix to adhere effectively to the surface of the device” (col. 8, lines 16-18), thereby teaching away from including a biologically active material in the primer layer. Thus, Harish does not disclose or suggest, and in fact teaches away from, applying to a surface of a medical device a coating composition comprising a biologically active material.

Additionally, Harish does not disclose or suggest a method for preparing an implantable medical device that includes “weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material.” Instead, Harish discloses the use of a technique that does not involve weighing or quantifying the amount of coating or biologically active material in the coating to be removed. In particular, Harish teaches that a “coating may be patterned such that portions of [the coating] positioned over at least some of [the gaps] are removed to yield a pattern of interstices dispersed between [the struts]. Such patterning of [the coating] may be accomplished, for example, by exposing designated portions of [the coating] to the discharge of a laser, such as an excimer laser.” (Col. 8, line 66 to col. 9, line 5). Therefore, Harish is teaching that the amount of coating to be removed is dictated by a desired pattern, such as one based on the interstices of the medical device, without first measuring the amount or quantity of coating that should be removed. By teaching the use of a technique which does not involve measuring or quantifying the amount of coating to be removed, Harish teaches away from the weighing step recited in claim 1.

For the above reasons, it is believed that claim 1 and claims 4, 5 and 12 depending therefrom are patentable over Harish. Accordingly, withdrawal of this rejection and allowance of claims 1, 4, 5, and 12 are respectfully requested.

## **II. REJECTION UNDER 35 U.S.C. § 103**

### **A. Claims 2, 6, 7, and 11 Are Patentable Over Graves**

Claims 2, 6, 7, and 11 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Graves. This rejection is respectfully traversed.

Claims 2, 6, 7, and 11 depend from claim 1 which was shown above to be allowable over Graves. As stated above, Graves does not disclose or suggest a method for manufacturing an implantable medical device that includes “weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material.” Moreover, as discussed above, since Graves teaches away from this weighing step, one of ordinary skill in the art would not find motivation in Graves to weigh a first medical device before and after application of a coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material to obtain the method of the present invention.

Thus, it is believed that claims 2, 6, 7, and 11 which depend from claim 1 are also allowable over Graves for the reasons discussed above. Accordingly, withdrawal of this rejection and allowance of claims 2, 6, 7, and 11 are respectfully requested.

### **B. Claims 2, 7 and 11 Are Patentable Over Harish**

Claims 2, 7 and 11 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Harish. This rejection is respectfully traversed.

Claims 2, 7, and 11 depend from claim 1 which was shown above to be allowable over Harish. As explained above, Harish does not disclose or suggest “applying to a portion of the surface of the first medical device a coating composition comprising the biologically active material in a manner such that a coating containing an amount of the biologically active material in excess of the desired amount of biologically active material is formed on the surface of the first medical device.”

Also, Harish, as discussed above, does not disclose or suggest, “weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material” as recited in claim 1. Additionally, one of ordinary skill in the art would not find motivation in Harish to obtain the method of the present invention because Harish teaches away from this weighing step.

For the above reasons, it is believed that claims 2, 7 and 11 are patentable over Harish. Accordingly, withdrawal of this rejection and allowance of claims 2, 7 and 11 are respectfully requested.

**C.     The Subject Matter Of Claim 3 Is Patentable Over Graves In View Of U.S. Patent No. 4,957,770 To Howarth**

Claim 3 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Graves in view of U.S. Patent No. 4,957,770 to Howarth (“Howarth”). This rejection is respectfully traversed. Cancellation of claim 3 obviates this rejection. As discussed above, the subject matter of canceled claim 3 has been incorporated into claim 1. It is believed that claim 1 is patentable over Graves in view of Howarth.

As discussed above, Graves does not disclose or suggest and in fact teaches away from “weighing the first medical device before and after application of the coating composition on the surface of the first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material” as recited in claim 1. Moreover, as the Examiner has recognized in the Office Action on page 8, Graves “fails to teach a method of determining the amount of bio-active material that is in excess.” Howarth does not remedy the deficiencies of Graves.

Howarth does not disclose or suggest a “method for manufacturing an implantable medical device having a surface adapted for exposure to body tissue of a patient, wherein at least a portion of the surface is covered with a coating having a desired amount of a biologically active material.” Howarth is not even directed towards an implantable medical device. The examples provided in the Howarth are related to coatings on paper sheets and do not include biologically active material. Thus, Howarth does not disclose or suggest a coating composition comprising a biologically active material. Since Howarth does not disclose or suggest an implantable medical device or a coating composition comprising a biologically active material, Howarth also does not disclose or suggest “weighing the first medical device before and after application of the coating composition on the surface of the

first medical device to determine the amount of biologically active material in the coating that is in excess of the desired amount of biologically active material" as recited in claim 1.

In addition, there is no motivation to combine the teachings of Graves and Howarth to obtain the present invention. In particular, as discussed above, Graves teaches away from weighing the coated medical device to determine the excess coating before removing the coating. Instead of first weighing or quantifying the amount of coating or biologically active material therein to be removed, Graves uses a stencil or masking technique, which does not involve weighing or quantifying the coating to be removed, to dictate the amount of coating that is removed. Therefore, assuming for the sake of argument that Howarth teaches weighing the medical device to determine the amount of excess biologically active material, which it does not, there is no motivation to combine such a weighing technique with Graves' teaching that a non-weighing technique, *i.e.*, stencil or masking technique, should be used to dictate the amount of coating to be removed.

For the above reasons, it is believed that amended claim 1 is patentable over Graves in view of Howarth. Accordingly, allowance of amended claim 1 is respectfully requested.

### **III. CLAIMS 8-10 AND 37-46**

The Examiner has stated that claims 8, 9, and 10 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 8-10 depend from claim 1 which has been amended herein. For the reasons discussed above, it is believed that present claims 8-10 are patentable over the cited references. Thus, withdrawal of this objection and allowance of claims 8-10 are respectfully requested.

Although Applicants disagree with the objection to original claims 8-10, Applicants have added new claims 37-39, which recite the subject matter of original claims 8-10, respectively, and the base and intervening claims. New claims 40-46 have also been added. Since claims 40-46 depend from claim 37 which is in condition for allowance, it is believed that claims 40-46 are also in condition for allowance.

**IV. CONCLUSION**

In light of the above amendments and remarks, it is believed that all the rejections of the claims have been overcome and that the present application is in condition for allowance. Should the Examiner not agree with Applicants' position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Enclosures

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